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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: RICHARD EUSTIS FULTON III and WILLIAM R. DUBRUL	Attorney Docket No.: ARTM 1000-5 Examiner: Unassigned Group: Unassigned
Application No.: Unassigned	
Filed: Concurrently Herewith	
Title: BIOPSY LOCALIZATION METHOD AND DEVICE	

BOX PATENT APPLICATION  
Assistant Commissioner for Patents  
Washington, D.C. 20231

**PRELIMINARY AMENDMENT**

Dear Sir:

Before the first action in this case, please amend this application as follows. Marked up copies of the amendments to the specification can be found in the attached Appendix.

**In The Specification**

Page 1, cancel the paragraph at lines 4-9 and substitute the following.

This application is a continuation of application No. 09/366,360 filed June 18, 1999, which application claims the benefit of the following Provisional patent applications. Biopsy Localization Device, Application No. 60/090,243, filed June 22, 1998; Biopsy Localization and Hemostasis Device, Application No. 60/092,734, filed July 14, 1998; Device and Method of Biopsy Localization and Hemostasis, Application No. 60/114,863, filed January 6, 1999; and Device and Method of Biopsy Localization, Hemostasis & Cancer Therapy, Application No. 60/117,421, filed January 27, 1999.

In The Claims

Please cancel Claims 1-52 and add Claims 53-88 as follows.

1        53.    A biopsy localization device comprising:

2                a bioabsorbable element in a pre-delivery state prior to its delivery to a

3 soft tissue biopsy site of a patient; and

4                said bioabsorbable element being of a material which is in a post-delivery state

5 at the biopsy site, the bioabsorbable element being at least one of palpably harder than or

6 remotely visualizable within the surrounding soft tissue at the biopsy site when in the post-

7 delivery state.

1        54.    The device according to claim 53 wherein the bioabsorbable element has a

2 hardness of at least about 1.5 times as hard as breast tissue in the post-delivery state.

1        55.    The device according to claim 53 wherein the bioabsorbable element swells

2 about 50 to 1500 percent from the pre-delivery state to the post delivery state when placed in

3 contact with an aqueous liquid.

1        56.    The device according to claim 53 wherein the bioabsorbable element has a

2 longest dimension of at least about 0.5cm when in the post-delivery state.

1        57.    The device according to claim 53 wherein the bioabsorbable element

2 comprises a therapeutic agent, the therapeutic agent comprising at least a chosen one of a

3 chemotherapy agent, a radiation agent and a gene therapy agent.

1        58.    The device according to claim 53 wherein the bioabsorbable element

2 comprises reservoir means for subsequently receiving a therapeutic agent.

1        59.    The device according to claim 58 wherein the reservoir means comprises

2 reservoir means for receiving at least one of a radiation agent, a gene therapy agent and a

3 chemotherapy agent.

1        60.    The device according to claim 53 wherein the bioabsorbable element

2 comprises a bioabsorbable filament.

1        61.    The device according to claim 53 further comprising a marker element in

2 contact with the bioabsorbable element.

1        62.    The device according to claim 61 wherein the marker element is a radiopaque

2 marker element located generally centrally within the bioabsorbable element.

1        63.    The device according to claim 62 wherein the radiopaque marker element

2 is a chosen one of a permanent marker element and a temporary marker element.

1       64.    The device according to claim 53 wherein the bioabsorbable element has  
2 margins, said margins being roughened so to help prevent migration of the bioabsorbable  
3 element within soft tissue of a patient.

1       65.    The device according to claim 64 wherein the bioabsorbable element has  
2 filaments extending from the margins.

1       66.    The device according to claim 65 wherein the filaments are of same material  
2 as the bioabsorbable element.

1       67.    The device according to claim 53 wherein the bioabsorbable element is  
2 remotely visualizable in its post-delivery state by at least one of ultrasound, mammography  
3 and MRI.

1       68.    The device according to claim 53 wherein the bioabsorbable element is softer  
2 in its post-delivery state than in its pre-delivery state.

1       69.    A medical device comprising a locatable bioabsorbable element configured for  
2 positioning at a biopsy site at the time of taking a tissue sample from the biopsy site.

1       70.    A biopsy localization method comprising:  
2                   taking a tissue sample from a biopsy site within a patient;  
3                   positioning a bioabsorbable element at the biopsy site;  
4                   testing the tissue sample; and  
5                   if the testing indicates a need to do so relocating the biopsy site by finding the  
6 bioabsorbable element by at least one of the following:

7                   palpation of the patient to feel the bioabsorbable element;  
8                   locating inflammation at the biopsy site caused by the bioabsorbable  
9 element;

10                   following a bioabsorbable thread, the thread extending from the  
11 patient's skin to the bioabsorbable element; and  
12                   remotely visualizing the bioabsorbable element.

1       71.    The method according to claim 70 wherein the positioning step is carried out  
2 using said bioabsorbable element and a radiopaque marker.

1       72.    The device according to claim 71 wherein the radiopaque marker element  
2 is a chosen one of a permanent marker element and a temporary marker element.

1       73.    The method according to claim 70 wherein the remotely visualizing step is  
2 carried out to by at least one of ultrasound, mammography and MRI.

1           74. The method according to claim 70 further comprising the step of selecting the  
2 bioabsorbable element so that after positioning at the target site, the bioabsorbable element  
3 has a hardness of at least about 1.5 times as hard as the surrounding tissue.

1           75. The method according to claim 74 further comprising the step of effectively  
2 preventing blood from contacting the bioabsorbable element until the bioabsorbable element  
3 is positioned at the target site, the effectively preventing step being carried out by using a  
4 hemostatic bioabsorbable element having a non-hemostatic biodegradable outer layer.

1           76. The method according to claim 71 further comprising the step of placing a  
2 marker element at a generally central location within the bioabsorbable element.

1           77. A medical treatment method comprising:  
2                   taking a tissue sample from a biopsy site within a patient;  
3                   positioning a bioabsorbable element at the biopsy site at the time of the taking  
4 of the tissue sample;  
5                   testing the tissue sample;  
6                   if the testing indicates a need to do so, medically treating the biopsy site.

1           78. The method according to claim 77 wherein the medically treating step is  
2 carried out by at least one of:  
3                   injecting a radiation-emitting element at the vicinity of the target site;  
4                   externally irradiating the target site;  
5                   providing a triggering substance to the agent; and  
6                   removing additional tissue at the target site.

1           79. The method according to claim 77 wherein the medically treating step  
2 comprises delivering a therapeutic agent to the target site.

1           80. The method according to claim 79 wherein the delivering step is carried out  
2 using at least one of:  
3                   a chemotherapy agent;  
4                   a radiation-emitting element;  
5                   thermal energy;  
6                   ionization energy;  
7                   gene therapy;  
8                   vector therapy;  
9                   electrical therapy;  
10                  vibrational therapy; and  
11                  anti-angiogenesis.

1        81. The method according to claim 77 further comprising relocating the biopsy  
2 site by finding the bioabsorbable element.

1        82. The method according to claim 81 wherein the relocating step is carried out by  
2 a chosen one of palpation and remote visualization.

1        83. The method according to claim 81 wherein the relocating step is carried out by  
2 remote visualization using at least one of ultrasound, mammography and MRI.

1        84. The method according to claim 81 wherein the relocating step is carried out  
2 prior to the medically treating step.

1        85. The method according to claim 84 wherein the medical treating step comprises  
2 removal of tissue.

1        86. The method according to claim 77 wherein the positioning step is carried out  
2 using a remotely visulizable bioabsorbable element, and wherein the relocating step comprises  
3 guiding a treatment device to the bioabsorbable element by at least one of remote visualization  
4 and palpation.

1        87. The method according to claim 77 wherein the medically treating step  
2 comprises activating the site locatable by the bioabsorbable element.

1        88. The method according to claim 87 wherein the activating step is carried out by  
2 at least one of:

3            injecting a radiation-emitting element at the vicinity of the target site;  
4            externally irradiating the target site; and  
5            triggering a substance carried by the element.

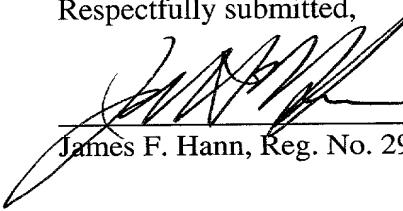
## REMARKS

Claims 53-88 remain in this case.

If the Examiner believes a telephone conversation would aid the prosecution of this  
case in any way, please call the undersigned at (650) 712-0340.

Respectfully submitted,

Dated: 6 July, 2001.

  
James F. Hann, Reg. No. 29,719

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## APPENDIX

The following is a marked up copy of the amended paragraph at lines 4-9 from page 1 of the specification.

This application is a continuation of application No. 09/366,360 filed June 18, 1999, which application claims the benefit of the following Provisional patent applications. Biopsy Localization Device, Application No. 60/090,243, filed June 22, 1998; Biopsy Localization and Hemostasis Device, Application No. 60/092,734, filed July 14, 1998; Device and Method of Biopsy Localization and Hemostasis, Application No. 60/114,863, filed January 6, 1999; and Device and Method of Biopsy Localization, Hemostasis & Cancer Therapy, Application No. 60/117,421, filed January [25] 27, 1999.